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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,149	01/19/2001	Eberhard Nieschlag	PLOVIN-3A	8178

23599 7590 09/05/2003

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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,149

Applicant(s)

NIESCHLAG ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 130-185 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 130-185 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/6/03 has been entered.

Specification

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 130-185 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guerin et al.

Guerin discloses the combination of progestagens and androgens and its use for male contraception (see abstract and entire article). The reference teaches progestagens such as medroxyprogesterone acetate and norethisterone and androgens such as testosterone and testosterone undecanoate (see page 188, lines 14-22). The reference also teaches (1) both steroid classes can be administered by intramuscular injections; (2) azoospermia or oligozoospermia are obtained (see page 188, lines 4-8) and (3) the use of various amount of each active agent.

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The instant claims differ from the reference by reciting various dosages of the active ingredient(s). However, the preparation of various pharmaceutical formulations having various amounts of the active agent is within the level of skill of one having ordinary skill in the art at the time of the invention. It is also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

Response to Arguments

Rejection under 35 U.S.C. 103 over Guerin

4. Applicant's arguments filed 6/6/03 have been fully considered but they are not persuasive. Applicants argue Guerin fails to teach non-oral administration. Also Guerin also teaches oral administration is the preferred administration route. It is the position of the examiner that while Guerin prefers oral administration, it is not the only mode of administration disclosed. Furthermore, Applicants themselves disclose on page 11 of the instant specification, while the method of preferred method of administration is by non-oral means, the method of administration is a means to an end, that is to say a method of delivering the formulation in any of its embodiments at an effective level, other methods of administration are anticipated. Therefore, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the mode of delivery based on the population, age, indented dose and length of administration.

5. Applicants also argue Guerin does not teach methods or compositions providing for an extended contraception effect, e.g. at least 4 weeks, upon single administration. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is

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noted that the features upon which applicant relies (i.e., "at least 4 weeks, upon single administration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Guerin discloses the administration of the hormone daily, wherein the protocols are disclose the daily administration of 0-3 months, 3-6 months and 6-18 months. Therefore, the daily administration of hormone would sustain the hormone in the blood for not less than 4 week as claimed by Applicant. Therefore, the rejection is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett: RMB
September 4, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1600